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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,508	08/01/2001	Tatsuo Kakimoto	Q65478	3296

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EXAMINER	
WOODWARD, CHERIE MICHELLE	
ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/918,508	KAKIMOTO ET AL.	
	Examiner	Art Unit	
	CHERIE M. WOODWARD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,20,21 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 20, 21, and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/22/2009 has been entered.

Formal Matters

2. Claims 1-8, 20, 21, and 28 are pending and under examination.

Response to Arguments

Claims Objections/Rejections Withdrawn

3. The rejection of claim 8 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendments.

Claim Objections/Rejections Maintained

Claim Rejections - 35 USC § 112, First Paragraph

Scope of Enablement

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-8 and 28 remain rejected under 35 USC 112, first paragraph, as lacking enablement commensurate in scope with the claims, for the reasons of record and the reasons set forth herein.

Applicant cites *Ex parte Kubin* (BPAI 2007) for the proposition that "claims having scope broader than the exact amino acid or nucleotide sequence disclosed should not be rejected under the enablement requirement of 35 USC 112, first paragraph" (Remarks, p. 12, first paragraph). Applicant's arguments has been fully considered, but it is not persuasive.

Applicant's "interpretation" of the *Kubin* decision is contrary to the opinion itself. Applicant does not site to any particular portion of *Kubin* to substantiate Applicant's interpretation. The portions of

Kubin applicable to Applicant's arguments state that an analysis of the *Wands* factors in light relevant case law is the applicable standard for an enablement analysis (*Kubin*, at 14). The enablement issue in *Kubin* centered around whether there was sufficient guidance in the specification and in the prior art for creating and screening 80% homologous mutants to the NAIL protein (*Kubin* at 10-11). The BPAI framed the enablement issue as "[c]onsidering the relevant Wands factors, including the prior art teachings cited by the Examiner and Appellants to establish the level of predictability in the relevant art, would undue experimentation have been required to practice the full scope of claim 73?" (*Kubin,* at 11). The analysis undertaken by the BPAI is nothing more than a restatement of the factors applied in *In re Wands* (858 F.2d 731, 736, 8 USPQ2d 1400, 1404 (Fed Cir 1988). See *Kubin,* at 14-15, stating that "the test for routine experimentation is not merely quantitative...if it is merely routine" Further, the *Kubin* decision restates the holding in *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1637, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986) stating that a "patent need not teach, and preferably omits, what is well known in the art" (*Kubin,* at 15). Accordingly, in contrast to the flawed analysis of Applicant's representative, the BPAI did not set forth any holding, statement, or even dicta, suggesting that "claims having scope broader than the exact amino acid or nucleotide sequence disclosed should not be rejected under the enablement requirement of 35 USC 112, first paragraph" (see Applicant's Remarks, p. 12, first paragraph). Instead, the BPAI did nothing more than restate the well-known enablement analysis that homologous sequences must be considered under both the *Wands* factors and the applicable teachings in both the specification and the art. Accordingly, Applicant's argument that the instant claims should not be rejected under 35 USC 112, first paragraph, enablement, is not supported by *Ex parte Kubin* or any other case law. The facts of this case have been and will continue to be analyzed under the *Wands* factors and the teachings in both the specification and the art. It is noted that Applicant previously presented arguments citing *Ex parte Kubin* and the examiner responded to them in the Office Action of 7/22/2008.

Applicant argues that the amendments to claim 8, subparts (g) and (h) and claim 28 are provided to advance prosecution (Remarks, p. 12, second paragraph to p. 13, second paragraph). Applicant's amendments and arguments have been fully considered, but they are not persuasive. Applicant did not separately or specifically address the rejections of claim 1-7.

Claims 1-8 and 28 encompass a broad genus of generic "cytokinin receptor genes" and variants. Cytokinins are plant hormones relevant to cell division and differentiation in higher plants. Applicant is enabled for cytokinin receptors that are known in the art and disclosed in the instant specification by SEQ ID NO and by a complete description of both the structure and function of the receptor, but neither the art nor the specification provide sufficient guidance regarding the full scope of the claimed generas of

cytokinin receptors. There is no teaching in the instant specification or the art relating the similarity of structure to conservation of function. General knowledge in the art includes the knowledge that some amino acid variations are tolerated without losing a protein's tertiary structure. However, conservation of structure is not necessarily a surrogate for conservation of function. In this case there is no guidance provided as to the correlation between structure and function.

Applicant is also referred to *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993), a 1985 application functionally claimed a method of producing protein in plant cells by expressing a foreign gene. The court stated: "[n]aturally, the specification must teach those of skill in the art `how to make and use the invention as broadly as it is claimed.'" *Id.* at 1050, 29 USPQ2d at 2013. Although protein expression in dicotyledonous plant cells was enabled, the claims covered any plant cell. Further, the breadth of the claimed genus of "cytokinin receptors" is not enabled by the instant specification or the art because the claims read on inoperative subject matter that is not known and has not yet been discovered. Applicant is reminded that broad claims may be rejected merely because they read on a significant number of inoperative species (see *In re Cook and Merigold*, 169 USPQ 298 (CCPA 1971)). See also, *In re Wright*, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993), the 1983 application disclosed a vaccine against the RNA tumor virus known as Prague Avian Sarcoma Virus, a member of the Rous Associated Virus family. The Federal Circuit held that the invention was not enabled for either all retroviruses or even for avian retroviruses. In *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991), the court found that several claims were not supported by an enabling disclosure "[t]aking into account the relatively incomplete understanding of the biology of cyanobacteria as of appellants' filing date, as well as the limited disclosure by appellants of the particular cyanobacterial genera operative in the claimed invention...." The claims at issue were not limited to any particular genus or species of cyanobacteria and the specification mentioned nine genera and the working examples employed one species of cyanobacteria. In *In re Colianni*, 561 F.2d 220, 222-23, 195 USPQ 150, 152 (CCPA 1977), the court affirmed a rejection under 35 U.S.C., first paragraph because the specification, which was directed to a method of mending a fractured bone by applying "sufficient" ultrasonic energy to the bone, did not define a "sufficient" dosage or teach one of ordinary skill how to select the appropriate intensity, frequency, or duration of the ultrasonic energy.

With regard to claim 8(h), Applicant has still not sufficiently taught the structure of the cytokinin receptors. The claim subpart reads on a cytokinin receptor with deletion, substitution, or additions of one or a plurality of amino acid where the amino acid sequence has 95% or higher identity to the amino acid sequence BEFORE the deletion, substitution or addition. Applicant is claiming a genus of cytokinin

receptors comprising 95% homologues of the sequences set forth in other parts of claim 8 where the 95% homology is only applicable to the sequence comparison BEFORE the deletions, substitutions, or additions. Claim 8(h) requires that the remaining structure (whatever that may be) still retain cytokinin activity, but Applicant entirely fails to provide any guidance as to the structure of the cytokinin receptor after the deletions, substitutions, or additions and no guidance is provided in the specification or the art as to which regions of cytokinin receptors are required to retain cytokinin receptor activity. As stated above and of record, there is no teaching in the instant specification or the art relating the similarity of structure to conservation of function. General knowledge in the art includes the knowledge that some amino acid variations are tolerated without losing a protein's tertiary structure. However, conservation of structure is not necessarily a surrogate for conservation of function. In this case there is no guidance provided as to the correlation between structure and function. Applicant has not complied with the *quid-pro-quo* requirements of providing adequate guidance about how to make and use the claimed invention in exchange for patentability.

With regard to claims 8(h) and 28, as explained of record, the sequence listing shows SEQ ID NOs: 1, 3, and 5 to be the nucleic acids and corresponding amino acid sequences for cytokinin receptors AHK2, AHK3, and CRE1, respectively. However, there is no teaching or guidance in the specification or in the art as to how these cytokinin receptors can be encoded by the polynucleotide complementary to SEQ ID NOs: 1, 3, and 5. The amended claims read "wherein said cytokinin receptor is encoded by the polynucleotide that hybridizes…to the polynucleotide complementary to the nucleotide sequence selected from the group consisting of SEQ ID NOs: 1, 3, and 5…" [Emphasis added.] Stated another way, if SEQ ID NOs: 1, 3, and 5, recite the nucleic acid structure of the cytokinin receptors AHK2, AHK3, and CRE1, respectively, it is unclear how the complementary nucleic acid structures also encode these cytokinin receptors. Nucleic acids complementary to the recited SEQ ID NOs will encode entirely different proteins than the ones disclosed in the instant specification and in the art as cytokinin receptors. There is no support in the specification for these complementary nucleic acids (see also the New Matter rejection, below). Additionally, the examiner repeats the statements of record that the "stringent conditions" set forth by Applicant in claims 8(h) and 28 will permit as little as 50% nucleic acid binding. The lack of specific binding will permit hybridization with any number of entirely unrelated nucleic acids, probes, primers. It would require undue experimentation to make and test the full scope of cytokine receptors of claims 8(h) and 28 where the post-deletion, substitution, or addition sequence is not known or taught anywhere in the art or the specification and where the hybridization requirements permit binding of nucleic acids that bind at only around 50%, and test the same for cytokinin activity.

With regard to claim 8(g), Applicant's amendments to claim 8(g) find support on page 26, second paragraph of the specification. However, Applicant does not provide sufficient guidance on how to "derive" receiver regions from the recited histidine kinases. The term "derived" indicates that the histidine kinases from the recited genes are to be manipulated or structurally changed in some way. In order to overcome the examiner's concern over the "derived" receiver regions, it is suggested that the phrase "are derived from" in claim 8(g) be replaced with the word "comprise."

Due to the large quantity of experimentation necessary to generate the large number of generic cytokinin receptors, structurally vague variants, and 50% complementary nucleic acid binding partners and screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features that are required to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the unpredictability of the claims which fail to recite sufficient structural limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 112, First Paragraph

Written Description

6. Claims 1-8, 20, 21, and 28 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for the reasons of record and the reasons set forth herein.

Applicant argues that the amendments to claims 8(g) and (h) and 28 overcome the instant rejections. Applicant's arguments have been fully considered, but they are not persuasive.

Applicant's amendments to claims 8(g) and (h) and 28 do not address the pending rejections of claims 1-7, 20, or 21. Further, Applicant's amendments are not persuasive.

Claims 1-8, 20, and 21 and 28 encompass a broad genus of generic "cytokinin receptor genes" and variants. Cytokinins are plant hormones relevant to cell division and differentiation in higher plants. Applicant has described the cytokinin receptors that are known in the art and are specifically disclosed in the instant specification by SEQ ID NO and by a complete description of both the structure and function of the receptor. However, neither the art nor the specification provide sufficient descriptions of the full scope of the claimed genus of cytokinin receptors.

With regard to claim 8(g), Applicant's amendments to claim 8(g) find support on page 26, second paragraph of the specification. However, Applicant does not provide sufficient description of how to

"derive" receiver regions from the recited histidine kinases. The term "derived" indicates that the histidine kinases from the recited genes are to be manipulated or structurally changed in some way. In order to overcome the examiner's concern over the "derived" receiver regions, it is suggested that the phrase "are derived from" in claim 8(g) be replaced with the word "comprise."

With regard to claim 8(h), Applicant has still not sufficiently described the structure of the claimed cytokinin receptors. The claim subpart reads on a cytokinin receptor with deletion, substitution, or additions of one or a plurality of amino acid where the amino acid sequence has 95% or higher identity to the amino acid sequence BEFORE the deletion, substitution or addition. Applicant is claiming a genus of cytokinin receptors comprising 95% homologues of the sequences set forth in other parts of claim 8 where the 95% homology is only applicable to the sequence comparison BEFORE the deletions, substitutions, or additions. Claim 8(h) requires that the remaining structure (whatever that may be) still retain cytokinin activity, but Applicant entirely fails to provide any description as to the structure of the cytokinin receptor after the deletions, substitutions, or additions and no description is provided in the specification or the art as to which regions of the claimed genera of cytokinin receptors are required to retain cytokinin receptor activity. Applicant has not complied with the *quid-pro-quo* requirements of providing adequate written description of the claimed invention in exchange for patentability.

With regard to claims 8(h) and 28, as explained of record, the sequence listing shows SEQ ID NOs: 1, 3, and 5 to be the nucleic acids and corresponding amino acid sequences for cytokinin receptors AHK2, AHK3, and CRE1, respectively. However, there is no adequate description in the specification or in the art as to how these cytokinin receptors can be encoded by the polynucleotide complementary to SEQ ID NOs: 1, 3, and 5. The amended claims read "wherein said cytokinin receptor is encoded by the polynucleotide that hybridizes…to the polynucleotide complementary to the nucleotide sequence selected from the group consisting of SEQ ID NOs: 1, 3, and 5…" [Emphasis added.] Stated another way, if SEQ ID NOs: 1, 3, and 5, recite the nucleic acid structure of the cytokinin receptors AHK2, AHK3, and CRE1, respectively, it is unclear how the complementary nucleic acid structures also encode these cytokinin receptors. Nucleic acids complementary to the recited SEQ ID NOs will encode entirely different proteins than the ones disclosed in the instant specification and in the art as cytokinin receptors. There is no description in the specification for these complementary nucleic acids (see also the New Matter rejection, below).

As previously stated of record, there are three species of the claimed genus disclosed that is within the scope of the claimed genus, *i.e.* SEQ ID NOs: 2, 4, and 6 (and corresponding nucleic acid sequences SEQ ID NOs: 1, 3, and 5). However, instant claims 1-8, 20, 21, and 28 encompass a genus of

cytokinin receptors, including variants and chimeras, that are not otherwise described in the specification. There is no disclosure in the instant specification or the art relating the similarity of structure to conservation of function. General knowledge in the art includes the knowledge that some amino acid variations are tolerated without losing a protein's tertiary structure. However, conservation of structure is not necessarily a surrogate for conservation of function. In this case there is no disclosed correlation between structure and function.

In the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus. One of skill in the art would not recognize from the disclosure that the applicant was in possession of the claimed genus. Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features (see, *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1895 (Fed. Cir. 2004); accord *Ex Parte Kubin*, 2007-0819, BPAI 31 May 2007, opinion at p. 16, paragraph 1).

New Claim Rejections - Necessitated by Amendment

Claim Rejections - 35 USC § 112, First Paragraph

Written Description – New Matter

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 8 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

As explained of record and above, the sequence listing shows SEQ ID NOs: 1, 3, and 5 to be the nucleic acids and corresponding amino acid sequences for cytokinin receptors AHK2, AHK3, and CRE1, respectively. However, there is no description in the specification or in the art as to how these cytokinin receptors can be encoded by the polynucleotide complementary to SEQ ID NOs: 1, 3, and 5. The amended claims as "wherein said cytokinin receptor is encoded by the polynucleotide that hybridizes…to the polynucleotide complementary to the nucleotide sequence selected from the group consisting of SEQ

ID NOs: 1, 3, and 5…" [Emphasis added.] Stated another way, if SEQ ID NOs: 1, 3, and 5, recite the nucleic acid structure of the cytokinin receptors AHK2, AHK3, and CRE1, respectively, it is unclear how the complementary nucleic acid structures also encode these cytokinin receptors. Nucleic acids complementary to the recited SEQ ID NOs will encode entirely different proteins than the ones disclosed in the instant specification and in the art as cytokinin receptors. There is no support in the specification for these complementary nucleic acids. Applicant did not identify any support in the Remarks filed 1/22/2009 and the examiner could not locate any support in the specification.

Conclusion

NO CLAIMS ARE ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:30am-6:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647